

REMARKS

Claims 1 and 6 have been amended to recite "extracted from" rather than "derived from." Thus, Claims 1, 2 and 5-7 remain pending in the present application. Support for the claim amendments may be found throughout the specification, for example at pages 18 and 19. No new matter has been added. Reconsideration and withdrawal of the present rejections in view of the comments presented herein are respectfully requested.

Evidence provided with response filed on July 1, 2009

In the Advisory Action, the Examiner stated that the evidence filed after the final action would not be entered. Applicants respectfully request consideration of this evidence, in addition to the remarks presented herein.

Rejection under 35 U.S.C. § 103(a)

The rejection of Claims 1, 2 and 5-7 as allegedly being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.* 46:3875-3878, 1998) and Xia (CN1435125; Derwent Acc No 2004-023802) in view of Suzuki et al. (*J. Agric. Food Chem.* 48:5649-5653, 2000) and in further view of Iwasaki et al. (US 7,014,876) was maintained.

The pending claims recite a method of reduction of triglyceride levels by administering a functional beverage (claim 1) or composition (claim 6) comprising the recited methylated catechins and extracted from the recited list of tea leaves. The present invention relates, in part, to Applicants' discovery that methylated catechins are unexpectedly much better than non-methylated catechins at reducing triglyceride (TG) levels. Based on this unexpected discovery, they identified the varieties of tea listed in Claims 1 and 6 that have high levels of methylated catechins, and selected these teas for reducing triglyceride levels. Nothing in the prior art would lead one of ordinary skill in the art to select the presently claimed types of teas.

a. Unexpected Results

The unexpected results obtained by Applicants' invention were reported both in Applicants' specification and in the Partial Translation of Reference Documents 1 and 2 submitted with Applicant's previous response. Specifically, the specification discloses in Example 3 on pages 24-25 that a test group given a beverage high in methyl catechins derived from "Benifuuki" tea had dramatically lowered triglyceride levels compared to a control group given a beverage low in methyl catechins derived from Barley tea. Although Barley tea is low in methyl catechins, barley tea is

known to contain significant of levels of catechins. See the attached abstract of Baik, J. Ag. Food Chem. 54:9978-9984 (2006) obtained at <http://cat.inist.fr/?aModele=afficheN&cpsidt=18368307>. Thus, an unexpectedly higher level of TG reduction was found in the group given a tea high in methyl catechins compared to the group given tea low in methyl catechins.

Moreover, Reference Document 1 reports similar results when a high methyl catechin tea, such as "Benifuuki" is compared with a low methyl catechin tea, such as "Yabukita." Table 1 of Reference Document 1 reports the results for a number of parameters in the two different groups, including "neutral fat," which is another term for triglycerides. A control group not receiving any additive had an average neutral fat level of 61.5 mg/dL. The "Yabukita" group had virtually the same neutral fat level at 61.2 mg/dL. In contrast, the "Benifuuki" group, had a more than 20% reduction, at 50.0 mg/dL.

Based on the discovery that teas high in methyl catechins have a significant TG-lowering effect, while teas low in methyl catechins have little effect on TG, Applicants identified the recited varieties of teas as those having high levels of methyl catechins. These particular teas have unexpectedly high levels of TG-lowering effect. As nothing in the prior art would lead one having ordinary skill in the art to expect such results, the unexpected results obtained by the presently claimed invention would rebut a *prima facie* showing of obviousness, even were such a showing established.

The Zeyuan reference cited by the Examiner actually further supports the unexpected effects of the presently claimed invention. This reference shows that black tea had a relatively moderate level of TG-lowering effect, while the corresponding green tea had a significantly greater TG-lowering effect. As described in Reference Document 2 attached to Applicants' previous response, the fermentation process involved in producing black tea from green tea substantially eliminates methyl catechins from the tea. Absent Applicants' discovery that teas high in methyl catechins produce an unexpectedly high level of TG-reduction, nothing in the Zeyuan reference would lead one having ordinary skill in the art to believe that the difference in TG-lowering effect results from differences in levels of methyl catechins. Thus, the difference in TG-lowering effects between the black tea and the green tea shown in the Zeyuan reference supports the unexpected results observed by Applicants.

b. The Combination of References Does Not Suggest the Claimed Invention

The two primary references, Zeyuan et al. and Xia, do not disclose or suggest methylated catechins. Zeyuan et al. teach that black tea lowers TG levels. Xia discloses that oolong tea, in

combination with a number of other ingredients, can be used to lower TG levels. However, nothing in Zeyuan et al. or Xia suggests that green teas high in methylated catechins, including the tea varieties recited in the present claims should be selected, or that there is any specific relationship between the ingredient contained in oolong tea and the effect of reducing blood triglyceride levels. Moreover, according to Chemistry and Function of Green tea, Black Tea, and Oolong Tea, Kougaku Shuppan, 1991, p. 27 (enclosed herewith, along with a partial English translation), the content of catechins found in fermented tea leaves of oolong tea is 45 to 70% less than in green teas. In view of this disclosure, the presently claimed catechins would be expected to exist only in trace amounts in the oolong teas disclosed by Xia et al.

Suzuki et al. disclose that a methylated catechin extract obtained from Benihomare and tong ting tea leaves has an anti-allergy effect. However, this reference does not teach or suggest that such an extract has any effect whatsoever on TG levels. Iwasaki et al. teaches an amount of catechin contained in oolong tea, but does not disclose anything about effective amounts of methylated catechins for reducing triglyceride levels. In addition, since the type and content of methylated catechins is different for each variety of tea recited in claim 1, the effect of reducing triglyceride levels in a beverage in Iwasaki et al. is determined based on the type of tea leaf consumed. In fact, in view of the teaching of the enclosed reference, the oolong tea disclosed by Iwasaki et al would not be expected to lower triglyceride levels since it contains only trace amounts of catechins.

In the absence of the inventors' teachings, one having ordinary skill in the art would not have any reason to select the particular varieties recited in the present claims out of all the many varieties of tea, because such a person would not know to select the varieties that have high levels of methyl catechins. It is only based on the disclosure of the present application that one of ordinary skill in the art would know to select specific varieties of tea, i.e. those with high levels of the recited methylated catechins, for the unexpected result of lowering TG levels. Thus, the claims cannot be obvious in view of the cited combination of references.

c. Conclusion of Nonobviousness

Even if the references had suggested the use of the recited methyl catechins derived from the recited varieties of tea for the reduction of TG levels, the unexpected results discussed above, would rebut any *prima facie* showing of obviousness raised thereby. Accordingly, in view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicants submit that all claims are in condition for allowance. However, if minor matters remain, the Examiner is invited to contact the undersigned at the telephone number provided below. If any additional fees are required, please charge these to Deposit Account No. 11-1410. Should there be any questions concerning this application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 7/31/09

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- 20) 柳田泉雄 著、堀江、万代雄訳、許谷 監、公孫樹子集、平栗?、779頁(1986)。
 - 21) 長谷川町子、村松道平編、中川政一、津和野、80、29(2002)。
 - 22) 中川政一、玉田寛二、谷本健二、85頁(1978)。
 - 23) 中川政一、長谷川町子編、88、38(1980)。
 - 24) 長谷川町子、萩原正太郎、増田善吾、阪本浩介、伊藤和夫、日本文学、34、20(1987)。
 - 25) 矢野龍一、八木隆一郎、西澤照太郎、小島茂樹、食料、42、43(1985)。
- (4) Goto, T., Yoshida, Y., Kuroi M., and Nagashima, J.: *J. Commerce*, A, 749, 286(1989).

- 20) 廣安文芸文庫 佐藤 萬代藏書, 清谷 啓: 公田村詩文集, 平成7・17(1995/1995).
- 21) 神谷真木, 中井清之: 高橋翁, 89, 26 (2000).
- 22) 尾崎士郎, 玉田富子: 交遊集, 50, 51 (1979).
- 23) 中川政之: 斎藤氏藏書, 58, 38 (1983).
- 24) 寺田忠太郎: 朝田良彦, 明治時代, 松本藩令, 伊奈幸夫, 3・4, 20 (1997).
- 25) 芝原由一: 入道歌, 酒類知識, 松本藩令, 小島孝之: 食料, 42, 419 (1995).
- 26) Goto, T., Yoshida, Y., Kato, M., and Yabebara H.: J. Chromatog., 8, 749, 205 (1956).

IV. 烏龍茶の成分化学

たのは20世紀も半ば以降のことである。これは向龍茶が中国の茶葉生産量(30万トン)の2～5%と低いことも理由の一つと考えられる。

愛媛県と佐賀県は、中国大陸福建省の武夷山地区（北閩地区、長興省称）、福建省（南閩地区）閩清縣、閩侯縣、閩縣、閩江流域、貴州省など日本人移住の熱い、広東地区、広西地区（仲安地区、台湾省、花蓮縣、花蓮市）の4地区に限られ、台湾省は、中国大陸福建省の武夷山地区に比べれば遠くはなれたとみえられている。

近年、わが国では戦前々への移住が盛んになり、それともなうて化平的の移住成果も発表されるようになった。

[illegible]

1. カテキン類と関連化合物

(1) カテキン類と誘導体

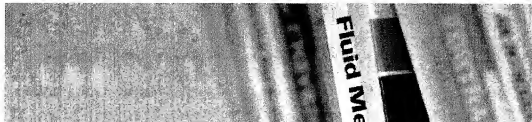
[illegible]

IV. COMPONENT CHEMISTRY OF OOLONG TEA

Takayanagi et al.¹ analyzed catechins contained in Taiwanese oolong tea and pouchong teas, manufactured in 1979 and 1980, and found that oolong teas, when fermented, have a catechin content of 45 to 70% less than that of green teas, and pouchong teas, when fermented, have a catechin content of 25% less than that of green teas, suggesting that pouchong teas are fermented mildly.

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**Titre du document / Document title**

Phenolic compounds of barley grain and their implication in food product discoloration

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Résumé / Abstract

Barley grains contain significant amounts of phenolic compounds that may play a major role in the discoloration of food products. Phenolic acid and proanthocyanidin (PA) composition of 11 barley genotypes were determined, using high-performance liquid chromatography and liquid chromatography-mass spectrometry, and their significance on food discoloration was evaluated. Abraded grains contained 146-410 µg/g of phenolic acids (caffeic, p-coumaric, and ferulic) in hulled barley and 182-282 µg/g in hullless barley. Hulled PA-containing and PA-free genotypes had comparable phenolic acid contents. Catechin and six major barley PAs, including dimeric prodelphinidin B3 and procyanidin B3, and four trimers were quantified. PAs were quantified as catechin equivalents (CE). The catechin content was higher in hullless (48-71 µg/g) than in hulled (32-37 µg/g) genotypes. The total PA content of abraded barley grains ranged from 169 to 395 µg CE/g in PA-containing hulled and hullless genotypes. Major PAs were prodelphinidin B3 (39-109 µg CE/g) and procyanidin B3 (40-99 µg CE/g). The contents of trimeric PAs including procyanidin C2 ranged from 53 to 151 µg CE/g. Discoloration of barley flour dough correlated with the catechin content of abraded grains ($r = -0.932$, $P < 0.001$), but not with the content of individual phenolic acids and PAs. Discoloration of barley flour dough was, however, intensified when total PA extracts and catechin or dimeric PA fractions were added into PA-free barley flour. The brightness of dough also decreased when the total PA extract or trimeric PA fraction was added into heat-treated PA-free barley flour. Despite its low concentration, catechin appears to exert the largest influence on the discoloration of barley flour dough among phenolic compounds.

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Mots-clés français / French Keywords

Spermatophyta; Angiospermae; Monocotyledones; Gramineae; Polyphénol; Catéchine; Flavanol; Flavonoïde; Proanthocyanidine; Acide phénolique; Décoloration; Aliment; Hordeum vulgare; Céréale; Orge; Phénols;

Mots-clés espagnols / Spanish Keywords

Spermatophyta; Angiospermae; Monocotyledones; Gramineae; Polifenol; Catequina; Flavanol; Flavonoide; Proantocianidina; Acido fenólico; Decoloración; Alimento; Hordeum vulgare; Cereal; Cebada; Fenoles;

Mots-clés d'auteur / Author Keywords

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